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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/473,165 12/28/99 HIGUCHI

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023594  
JOHN S. PRATT  
KILPATRICK STOCKTON LLP  
1100 PEACHTREE  
SUITE 2800  
ATLANTA GA 30309

IM22/0911

EXAMINER

CROSS, I

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

09/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/473,165

Applicant(s)

HIGUCHI ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This Office Action is in response to Applicants' amendments filed on June 25, 2001 and entered as Paper No. 8. Claims 6-8 and 10-13 are pending in the instant application.

#### ***Withdrawal of Rejections from Previous Office Action***

The rejection of claims 10 and 13 under 35 USC 112, second paragraph is withdrawn in view of Applicants' amendments to correct the indefiniteness of the claims.

The rejection of claims 6 and 7 under 35 USC 102 over Arai et al '347 is withdrawn in view of Applicant's amendments to the claim to specify that the light blocking layer contains particles in the form of polymer beads embedding the particles.

#### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arai et al '347.

Arai et al '347 teach a multi-layer analysis element containing at least one hydrophilic polymer layer and a spreading layer on the hydrophilic layer. The hydrophilic layer contains colorimetric reagents and serves as the reagent layer (col. 3, lines 10-17). The multi-layer system also provides for a light-shielding (light-blocking) layer on the reagent layer. The light-shielding layer contains light shielding particles

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such as carbon black (col. 4, lines 39-62). Arai et al '347 further disclose that the light shielding layer is formed of fine particles (such as carbon black) dispersed in hydrophilic polymer binders such as polyvinyl alcohol (col. 3, lines 1-5 and col. 4, lines 39-47). At col. 5, lines 4-15, Arai et al '347 teach that the ratio of hydrophilic polymer binder to light-shielding particles is about 2.5-7.5 to 10. Arai et al '347 also disclose that single layers may be made to serve two or more functions (col. 3, lines 44-50).

Arai et al '347 differ from the instantly claimed invention in that the limitation of embedding the light-shielding particles in polymeric beads is not explicitly disclosed. However, Arai et al '347 disclose that light shielding particles are dispersed into a polymer and coated onto the reagent layer to dry. It is the position of the Examiner that the dispersion of light shielding particles into the polymer is equivalent to embedding the particles in polymers, absent evidence to the contrary. Applicants state at page 34, lines 20-25 of the instant specification, that light-blocking particles embedded into polymeric beads are commercially available. Thus, absent evidence of unexpected results in using "embedded" particles over "dispersed" particles, it is submitted that one of ordinary skill in the art would consider both to be equivalent and it would be obvious to choose either in preparing the multi-layer test system.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious within meaning of 35 USC 103 in view of the teachings of Arai et al '347.

***Response to Arguments***

2. Applicant's arguments filed June 25, 2001 have been fully considered but they are not persuasive.

Applicants' arguments concerning the rejection under 35 USC 103 over Arai et al '347 is directed to the reference's use of light blocking particles dispersed in a polymer, as opposed to Applicants' claimed light blocking particles embedded in a polymer. Applicants' have submitted a declaration under 37 CFR 1.132 showing the effects of the two. Applicants' declaration however, fails to show any substantial unexpected results. Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co., Inc.*, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Applicants' evidence shows a difference of only a few seconds in using light blocking particles dispersed in a polymer (Arai et al '347) as opposed to light blocking particles embedded in a polymer. With respect to the hematocrit values, Applicants have argued that a lower influence of hematocrit values on reflectance results when embedded particles are used. Again, the difference in influences, as shown by the third graph in Applicants' declaration, is quite small. As the courts have held, differences between the claimed invention and the prior art are to be expected. Applicants have the burden of showing that such differences are substantially unexpected. It is the position of the Examiner that the data presented fails to show a substantial difference in using dispersed particles rather than embedded particles.

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3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is (703) 305-7360. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-5408.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

LIC  
September 9, 2001

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700